87-1194

No.

IN THE

Supreme Court of the United States

OCTOBER TERM, 1987

THE COSMETIC, TOILETRY AND FRAGRANCE ASSOCIATION,
Petitioner,

v.

PUBLIC CITIZEN, *et al.*,
Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

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QUESTION PRESENTED

Did the Food and Drug Administration act unreasonably in construing the anticancer provision in the Federal Food, Drug, and Cosmetic Act—commonly known as the Delaney Clause, 21 U.S.C. § 376(b)(5)(B)—to permit the approval of color additives that FDA has determined present a *de minimis* risk, such as one in 19 billion, and thus "impose no additional risk of cancer to the public."

PARTIES TO THE PROCEEDING

Petitioner, The Cosmetic, Toiletry and Fragrance Association, Inc., a national trade association representing the cosmetic industry, petitioned the Food and Drug Administration for approval of the color additives at issue. CTFA intervened as a respondent in the court below.*

Respondents Public Citizen, Nancy Hendree Simpson, Phillip L. Weinberg, and Mary Lou Rooney were petitioners in the court below, seeking review of regulations issued by the Food and Drug Administration granting permanent approval to the color additives at issue.

Respondents Dr. Frank Young and Dr. Otis Bowen are Commissioner of Food and Drugs and Secretary of Health and Human Services, respectively. In their official capacities, they were respondents in the court below.

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* * CTFA has no parent companies, subsidiaries, or other affiliates.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

The Cosmetic, Toiletry and Fragrance Association petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-34a) is reported at 831 F.2d 1108. The final rules of the Food and Drug Administration (Pet. App. 35a-97a, 98a-167a) are published at 51 Fed. Reg. 28331, 28346 (Aug. 7, 1986). A notice rejecting objections to the final rules (Pet. App. 168a-172a) is published at 51 Fed. Reg. 35509 (Oct. 6, 1986). Clarifications of the preambles to the final rules (Pet. App. 173a-178a, 179a-184a) are published at 52 Fed. Reg. 5081, 5083 (Feb. 19, 1987).

JURISDICTION

The judgment of the court of appeals (Pet. App. 185a-186a) was entered on October 23, 1987. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

Section 706 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 376, is reprinted at Pet. App. 187a-203a.

STATEMENT

The court of appeals granted a petition for review filed by Public Citizen and three individuals challenging final regulations of the Food and Drug Administration (FDA) granting permanent "listing" (approval) to two color additives, D&C Orange No. 17 and D&C Red No. 19.[1] The listing decisions were made on the basis of FDA's *de minimis* policy, under which the agency will approve additives that present only a negligible or trivial carcinogenic risk to humans.

The Cosmetic, Toiletry and Fragrance Association (CTFA), a national trade association representing the cosmetic industry,[2] petitioned FDA for permanent listing of the color additives, and it intervened as a respondent in the court of appeals. Most of the existing data concerning these and other color additives for which approval has been sought were generated under a multi-million dollar testing program sponsored and financed by CTFA. CTFA member companies, which include the nation's largest manufacturers of cosmetics, have been major users of the color additives in question.

In addition to the color additives in issue here, FDA has permanently listed two other color additives, D&C Red Nos. 8 and 9, on the basis of the *de minimis* policy. Public Citizen has challenged that decision in the United States Court of Appeals for the Third Circuit. *Public Citizen* v. *FDA*, No. 87-3507. Recognizing that "the case

[1] "D&C" additives are approved for drug and cosmetic uses; "FD&C" additives are approved for food uses as well.

[2] CTFA includes more than 250 active member companies, which manufacture or distribute an estimated 90 percent of the total volume of finished cosmetic products sold in the United States. In addition, CTFA includes more than 240 associate member companies from related industries, such as manufacturers of cosmetic raw materials, including color additives and packaging materials.

in the D.C. Circuit will determine whether the FDA may lawfully use the *de minimis* policy" (Motion for Stay at 2), Public Citizen moved to stay proceedings in that case pending review by this Court in the instant case, and its motion was granted.[3]

A. The Statutory Framework

The Color Additive Amendments of 1960, Pub. L No. 86-618, 74 Stat. 397, 21 U.S.C. § 376, were included in the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize comprehensive FDA regulation of color additive safety.[4] The Amendments provide for the permanent listing of additives that have been demonstrated to be safe for their intended uses.[5] FD&C Act § 706(b), 21 U.S.C. § 376(b). This general safety clause is similar to other provisions of the Act, such as the requirements that food additives, drugs, and animal drugs be safe for their

[3] FDA also has proposed to apply the *de minimis* policy to allow the continued use of the food additive methylene chloride, which is used to decaffeinate coffee. Public Citizen's challenge to that ongoing rulemaking was dismissed on ripeness grounds. Public Citizen v. Bowen, No. 86-1494 (D.C. Cir. Nov. 20, 1987).

[4] Color additives are important ingredients in many cosmetics and drug products, and their loss would have a major adverse impact on both industry and consumers. For example, color additives are used in drugs to distinguish one medication from another, and in shampoos, toothpaste, and mouthwash. Color additives also are significant components of lipsticks, rouge, nail polish and blushers. If the additives these cosmetics contain could no longer be used, the products could become unavailable.

[5] Recognizing the importance of color additives, Congress authorized their continued use while proof of safety is being developed. A special transitional section of the Amendments permits the continued use under "provisional listings" of color additives that were commercially established before the statute was enacted, including D&C Orange No. 17 and D&C Red No. 19. The legality of certain extensions of the provisional listing of several color additives was upheld in McIlwain v. Hayes, 690 F.2d 1041 (D.C. Cir. 1982), and was again upheld by the court of appeals in a case consolidated with the one addressing the permanent listing of D&C Orange No. 17 and D&C Red No. 19. *See* Pet. App. 30a-34a.

intended uses. *See* FD&C Act §§ 409, 505, 512; 21 U.S.C. §§ 348, 355, 360b.

In addition to the general safety provision for color additives, Congress stated that a color additive "shall be deemed unsafe, and shall not be listed" for ingested (internal) uses "if the additive is found by the Secretary [of Health and Human Services or his delegate, the Commissioner of Food and Drugs] to induce cancer when ingested by man or animal." For noningested (external) uses, Congress provided that an additive shall not be listed "if, after tests which are appropriate for the evaluation of the safety of additives for such use, . . . it is found by the Secretary to induce cancer in man or animal." FD&C Act § 706(b)(5)(B); 21 U.S.C. § 376(b)(5)(B). These provisions are known as the Delaney Clause.

The Delaney Clause had first been enacted in 1958 as part of the Food Additives Amendment to the FD&C Act. *See* FD&C Act § 409(c)(3)(A), 21 U.S.C. § 348(c)(3)(A). The 1960 enactment was based directly on the 1958 provision, and uses precisely the same language.[6] The Delaney Clause also applies to animal drugs. *See* FD&C Act § 512(d)(1)(H), 21 U.S.C. § 360b(d)(1)(H).

B. The Factual Basis For The *De Minimis* Policy

1. As this Court has recognized, "[r]isk is a pervasive element of modern life."[7] Since it is not possible to implement a regulatory policy of eliminating all risks, agencies must determine "what risks are acceptable in the world in which we live."[8] To make this determination in a

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[6] The provision applicable to noningested uses of color additives does not have a counterpart in the food additive Delaney Clause, because that clause applies only to ingested substances.

[7] Metropolitan Edison Co. v. People Against Nuclear Energy, 460 U.S. 76, 775 (1983).

[8] Natural Resources Defense Council, Inc. v. United States EPA, 824 F.2d 1146, 1164-1165 (D.C. Cir. 1987) (en banc); *see* Industrial Union Dep't, AFL-CIO v. American Petroleum Inst., 448 U.S. 607, 642 (1980) (plurality op.).

rational manner, agencies distinguish between the magnitudes of risk to the public presented by different substances under their jurisdiction. An important means of evaluating risk, relied on by scientific regulatory agencies since the early 1970s, is quantitative risk assessment. *See* Pet. App. 5a-6a n.2.

An understanding of the development of quantitative risk assessment is critical, because the court below failed to appreciate FDA's conclusion that this scientific method permits the agency to recognize substances that present *no* risk of cancer in humans. Relying on quantitative risk assessment, FDA has stated that it is able to identify substances—such as the color additives at issue here—that present 'trivial" levels of risk which are, "for all practical purposes, zero," and are therefore "the functional equivalent of no risk at all." Pet. App. 81a, 85a, 150a, 154a. Based on the advances in science that permit such risk calculations, FDA has concluded that it may exercise its discretion and "inherent authority under the *de minimis* doctrine" to adopt a policy under the Delaney Clause of not barring substances that can reliably be determined to "impose no additional risk of cancer to the public." *Id.* at 77a, 86a, 146a, 155a.

2. Quantitative risk assessment is the mathematical extrapolation of data from high-dose animal feeding studies to derive statistical estimates of the cancer risk associated with the much smaller amounts of a substance to which humans are exposed under actual conditions of use. Risk assessment involves four steps: identifying a hazard on the basis of animal studies; extrapolating from the high animal doses to predict human response at lower doses; assessing the degree of human exposure to the substance; and estimating the risk to humans on the basis of the dose-response curve, human exposure, and all other relevant information. *See* Pet. App. 4a-5a.

Because of uncertainties in the risk assessment process, assumptions must be made to fill gaps in the underlying scientific base. It is standard practice among scientists

and regulators to rely on highly conservative assumptions at each stage of the process. As FDA has stated, "[w]here science fails to provide solutions, FDA applies conservative assumptions to ensure that its decisions will not adversely affect the public health." 50 Fed. Reg. 45530, 45542 (1985); *see* Pet. App. 5a. In all, risk assessment produces "worst-case" estimates that may be many orders of magnitude (*i.e.*, thousands, millions, or more times) higher than any actual risk to humans. *See* C.A. App. 502-526.[9]

The risk assessments resulting from quantitative risk assessment are deliberately conservative statistical extrapolations. Because of its underlying conservative assumptions, an extrapolated risk is not directly comparable to an actuarial risk. *See* Pet. App. 85a-86a, 154a-155a. Actuarial risks are based on direct empirical data concerning the frequency of adverse events, such as the risk from working in a coal mine.[10] Actuarial data allow one to predict with a high degree of confidence that a given number of persons, such as one in one million, will suffer harm. *See* C.A. App. 527-529. In contrast, an extrapolated risk is a theoretical maximum designed to establish an unrealistically high upper-bound on the true risk. An extrapolated risk of one in one million does *not* mean that one person out of one million will contract cancer as a result of exposure to a particular substance. Rather, as FDA concluded, such a computed risk means, "in all likelihood, no one will contract cancer." Pet. App. 86a, 155a.

3. Laboratory tests of the color additives in question showed carcinogenicity in some test animals fed very high doses. CTFA therefore conducted quantitative risk assessments of these additives to evaluate their risk in

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[9] A copy of the joint appendix in the court of appeals has been lodged with the Clerk of this Court.

[10] Actuarial data are not available for exposure to substances such as the color additives in question because the risks involved are so small as to be nonexistent.

humans. Despite numerous conservative assumptions, which resulted in an overestimate of the risk, these calculations demonstrated that the additives present, at most, an extremely small risk to humans. *See* Pet. App. 4a; C.A. App. 55-56, 120. CTFA submitted this information to FDA in support of its petition for approval of the color additives.

To assist him in evaluating the safety of the color additives, the Commissioner of Food and Drugs appointed a Color Additive Scientific Review Panel, composed of noted government experts, to review all of the available data. Pet. App. 4a, 6a. In particular, the Panel "critically reviewed the risk assessments submitted by CTFA" and also performed its own risk assessments for the color additives. C.A. App. 167.[11]

The Panel concluded first that "risk assessments can be performed" for the color additives. C.A. App. 149. The Panel also determined that CTFA's calculations were "generally consistent with present methodologies used in risk assessment" and that it "basically agrees with the risk assessment methodology used by CTFA." *Id.* at 167. Like CTFA, the Panel, "following prudent public health policy, . . . tended to accept assumptions which are likely to overestimate rather than underestimate [the] risk." *Id.* at 188. Thus, for example, "where available data would allow for a choice between 'degrees of reasonable estimate', the Panel consistently selected the estimate associated with the higher risk." *Id.* at 217. *See* Pet. App. 64a, 74a, 129-130a, 138a.

From its quantitative risk assessments, the Panel concluded that D&C Orange No. 17 presents an upper-bound lifetime risk of cancer of no more than *one in 19 billion*

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[11] The Panel's report is reproduced at C.A. App. 139-333. It has been subjected to peer review and published in the scientific literature. R. Hart, *et al.*, "Final Report of the Color Additive Scientific Review Panel," 6 Risk Analysis 117 (1986). *See* Pet. App. 43a, 106a.

and that D&C Red No. 19 presents an upper-bound lifetime risk of cancer of no more than *one in 9 million*. Pet. App. 6a. These levels are considerably lower than the one-in-one-million level of risk that FDA and other agencies use as a benchmark for determining whether a substance presents an actual risk of cancer and therefore requires regulatory controls. *See id.* at 86a-90a, 156a-159a.

C. The Final Rules

1. On August 7, 1986, FDA published final rules permanently listing D&C Orange No. 17 and D&C Red No. 19 for use in externally applied drugs and cosmetics. Pet. App. 35a-97a, 98a-167a. The agency determined that the "theoretical carcinogenic risk" presented by the additives "is so trivial as to be effectively no risk at all." *Id.* at 43a, 106a. Accordingly, FDA concluded that the additives are safe and may be approved under the general safety standard and the Delaney Clause.

In reviewing CTFA's risk assessments, FDA noted that "[i]t was standard procedure by CTFA to make highly conservative 'worst case' assumptions at each step, so that the final estimates likely overstated the actual risks by large factors." Pet App. 62a-63a, 126a. For example, FDA found that CTFA's exposure estimates "greatly overestimate the extent of exposure" to the additives during actual use. *Id.* at 61a, 125a. FDA also reviewed the Panel's risk assessments, observing that the Panel "consistently selected the estimate associated with the higher risk" in choosing between different exposure assumptions. *Id.* at 74a, 138a.

FDA concluded, as a factual matter, that CTFA's risk calculations, as modified by the Panel, "represent a reliable upper bound risk" that "can be used to evaluate" the safety of the additives. Pet. App. 76a, 140a. The Panel's highest risk estimates, as noted above, are a one in 19 billion lifetime risk for D&C Orange No. 17 and a one in 9 million lifetime risk for D&C Red No. 19. FDA found that such a "trivial" level of risk is "the functional equi-

valent of no risk at all." *Id.* at 85a, 154a. The agency further found that the use of these additives "impose[s] no additional risk of cancer to the public" and is not of any "public health consequence." *Id.* at 86a, 155a. FDA emphasized that the risk estimates are so conservative and so low that, "in all likelihood, no one will contract cancer as a result of" exposure to these additives. *Id.* at 86a, 155a.

In view of these conclusions, FDA reasoned that "there is no gain to the public and the statutory purpose is not implemented or served" by interpreting the Delaney Clause to bar approval of the additives. Pet. App. 77a, 141a. Thus, FDA exercised its discretion and "inherent authority under the *de minimis* doctrine" to adopt a policy under the Delaney Clause of not barring substances that present a negligible theoretical risk of cancer to the public. *Id.* at 77a, 146a. FDA found that a one-in-one-million lifetime risk was an appropriate benchmark for application of the *de minimis* doctrine, which would give a wide margin of safety for the public. *Id.* at 86a-90a, 156a-159a. These additives present an even smaller lifetime risk, and FDA therefore approved them as safe for use.

2. Public Citizen objected to the final rules solely on legal grounds, and thereby waived its right to a hearing to contest the factual findings made by FDA concerning quantitative risk assessment and its application to the color additives in question. *See* C.A. App. 379, 382. Those findings therefore stand uncontested. *See* Pet. App. 7a; *see generally, e.g., United States* v. *L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952). FDA rejected Public Citizen's legal objections on October 6, 1986. Pet. App. 168a-172a.[12]

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[12] FDA subsequently filed notices clarifying the preambles to the final rules. Pet. App. 173a-178a, 179a-184a. In these notices, FDA stated that its *de minimis* policy is based on an interpretation of the term "induce cancer" in the Delaney Clause as well as on the agency's inherent authority.

D. The Court Of Appeals' Decision

On direct review pursuant to 21 U.S.C. §§ 371(f), 376(d), the court of appeals concluded, "with some reluctance" (Pet. App. 3a), that the *de minimis* policy exceeds FDA's statutory authority, and the court invalidated the regulations listing D&C Orange No. 17 and D&C Red No. 19. *Id.* at 1a-34a.

The court of appeals reached this conclusion even though it agreed with CTFA and FDA that "it seems altogether correct to characterize these risks [presented by the additives] as trivial." Pet. App. 7a. The court noted, for example, that a one-in-one-million lifetime risk (19,000 times higher than the risk for D&C Orange No. 17) is equivalent to the risk of cancer from eating "*one* peanut with the FDA-permitted level of aflatoxins once every *250* days." *Id.* (emphasis in original). As the court observed, persons "who indulge in [such risks] can hardly be thought of as living dangerously. Indeed, they are risks taken without a second thought . . . ." *Id.* Thus, "the risks posed by the two dyes would have to be characterized as 'acceptable.'" *Id.* at 10a.

In addition, the court of appeals explained that rejection of the *de minimis* policy may entail "a clear *loss* for safety." Pet. App. 11a (emphasis added). The reason for this conclusion is that an overly rigid interpretation of the Delaney Clause may force manufacturers to substitute comparatively toxic (but noncarcinogenic) color additives for safer additives that cannot be approved merely because they are associated with a trivial theoretical risk of cancer. *Id.* at 10a-11a.

The court also recognized that there is no need to find an explicit basis for the *de minimis* doctrine in the statutory language. Pet. App. 9a. It is enough that application of this doctrine would avoid "[i]mposition of pointless burdens on regulated entities" and the resulting "losses for their customers." *Id.* The court agreed that these purposes would be well served by the *de minimis*

policy in this case, since the policy would prevent "loss of access to the colors made possible by a broad range of dyes." *Id.* at 9a-10a; *see also id.* at 20a ("the legislation as a whole implicitly recognizes that color additives are of value"); *id.* at 21a ("in some uses color additives advance health").

Notwithstanding these considerations, the court of appeals concluded that application of the *de minimis* policy would not "tend[] to implement the legislative design of the color additive Delaney Clause." Pet. App. 11a. The court supported this result on the ground that, in its view, the legislative history "points powerfully against any *de minimis* exception." *Id.* at 12a. At the same time, however, the court acknowledged that the legislative history "is hardly conclusive." *Id.* at 19a. The court also advanced "some possible explanations for Congress's apparent rigidity," based primarily on public fears concerning cancer at the time that the provision was enacted. *Id.* at 19a-21a.

In reaching its decision, the court sought to distinguish two cases that had applied the *de minimis* policy with respect to regulation of food additives and color additives under the FD&C Act, *Monsanto Co.* v. *Kennedy*, 613 F.2d 947 (D.C. Cir. 1979), and *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984) (per curiam). Pet. App. 22a-24a. In *Monsanto*, the court ruled that the definition of "food additive" under the Act permits a *de minimis* exception, thus insulating substances within the exception from operation of the food additive Delaney Clause. In *Scott*, the court held that the Delaney Clause did not bar approval of color additives that contain contaminants presenting a *de minimis* carcinogenic risk. The court here conceded that these cases applied the *de minimis* doctrine "on the periphery of the Delaney Clauses," but it refused to follow their reasoning with respect to the "core operation" of these statutory provisions. *Id.* at 24a.

Finally, the court of appeals concluded that advances in scientific knowledge since enactment of the first Delaney Clause in 1958 did not provide a reasonable basis for the *de minimis* policy. Pet. App. 24a-27a.[13] The court acknowledged the "impressive array of food ingredients . . . found to be animal carcinogens" since 1958, but it sought to avoid disastrous implications for the food supply by concluding that the food additive Delaney Clause might be interpreted differently from the color additive Delaney Clause, despite their similar wording. The court further concluded that, in any event, FDA could return to Congress if a rigid interpretation of the Delaney Clause would "require a ban on dietary essentials." *Id.* at 24a, 27a.

REASONS FOR GRANTING THE PETITION

The decision below prohibits FDA from permitting the use of undeniably safe substances by holding that the Delaney anticancer provision is an absolute bar to approval of additives that "impose no additional risk of cancer to the public" (Pet. App. 86a, 155a). The court of appeals appeared to acknowledge the absurdity of this result, which contravenes both the legislative history of the statute and well-established principles of administrative law. Despite the court's disclaimers, its decision, if left undisturbed, will have significant ramifications for FDA and other federal agencies, industry, and consumers. Review by this Court is therefore warranted.

The court of appeals correctly recognized that any human risk presented by these color additives is "trivial." Pet. App. 7a. The court seriously erred, however, in concluding that FDA had no choice under the Delaney Clause but to ban the additives. As discussed below, the court simply did not consider relevant legislative history and it misunderstood the structure of the FD&C Act, both

[13] The court also rejected the position taken by FDA in its clarification of the preambles to the final rules that the *de minimis* policy is supported by an interpretation of the term "induce cancer" in the Delaney Clause. Pet. App. 27a-30a.

of which demonstrate that the Delaney Clause need not receive the irrational and burdensome construction imposed by the court of appeals.

A. The Court Of Appeals Erred By Holding That The Delaney Clause Prohibits Approval Of Substances That Do Not Present Any Risk Of Cancer To The Public

The court of appeals based its decision in large part on what it viewed as the "almost inescapable" language of the Delaney Clause. Pet. App. 8a. This argument is erroneous in three respects. First, the court of appeals misconceived the *de minimis* doctrine, which rests on an agency's *inherent* authority rather than on the statutory language and has for almost 75 years been a recognized feature of the federal food and drug laws. Second, the court completely ignored the crucial 1958 legislative history, where Congress stated that the statute *"reads and means the same with or without inclusion of the [Delaney] clause."* Third, the court failed to appreciate the significance of FDA's increasingly sophisticated methodology for regulating carcinogens.

Because of these errors, the court of appeals fundamentally misunderstood the Delaney Clause. That provision was never intended by Congress, and has never been interpreted by FDA, as the sweeping, absolute barrier that the court below considered it to be. There are numerous statutory and administrative exceptions to the Delaney Clause. For example, the Delaney Clause does not apply to the following substances:

- Substances shown to cause cancer in animals, if the animal models are not appropriate or relevant for the evaluation of safety in humans (*e.g.*, calcium causes cancer in bulls);
- Secondary carcinogens (*i.e.*, substances that cause a physiologic change which, in turn, causes cancer);

- Carcinogenic contaminants in food within established tolerances or action levels;
- Carcinogenic constituents of food additives and color additives if they pose a *de minimis* human risk;
- Carcinogenic animal drugs if their detectable residues pose a *de minimis* human risk;
- Carcinogenic substances that are not considered food additives because they are present in amounts that pose a *de minimis* human risk; and
- Carcinogens that are ubiquitous in the environment and are present as food additives or color additives in amounts that pose a *de minimis* additional human risk (*e.g.*, lead).

In view of these numerous exceptions, the Delaney Clause cannot be considered as a rigid, monolithic barrier to approval of substances that cause cancer in animals, regardless of their safety in humans. As explained below, the *de minimis* policy invalidated by the court of appeals is entirely consistent with these exceptions and with Congress's intent.

1. At least until the decision below, it was well-established that regulatory agencies have inherent authority to exclude *de minimis* matters from regulation, even where the underlying statute is "without exception or qualification." *Permian Basin Area Rate Cases*, 390 U.S. 747, 787 (1968). This Court established this principle with respect to food regulation in 1914, when it held that "a small addition of poisonous or deleterious ingredients" did not violate the seemingly absolute prohibition of "*any* added poisonous or other added deleterious ingredient which *may* render such [food] injurious to health." *United States* v. *Lexington Mill & Elevator Co.*, 232 U.S. 399, 410-411 (1914) (interpreting Food and Drugs Act of 1906, § 7, 34 Stat. 768, 770 (emphasis added)). In general, federal regulatory statutes—and the food and drug laws in particular (*see* pages 19-20,

infra)—are "intended to require the elimination, as far as feasible, of *significant* risks of harm" rather than "to eliminate completely and with absolute certainty any risk." *Industrial Union Dep't, AFL-CIO* v. *American Petroleum Institute*, 448 U.S. 607, 641 (1980) (plurality opinion) (emphasis added) (interpreting Occupational Safety and Health Act).[14] In view of the inescapable risks present in modern society (page 4, *supra*), it could scarcely be otherwise.

The court of appeals' decision is inconsistent with these principles. While the court paid lip service to the *de minimis* doctrine and even acknowledged that the doctrine would advance congressional policies underlying the FD&C Act (Pet. App. 9a-11a), the decision below effectively eliminates agency discretion to adopt and apply a *de minimis* policy, without sufficient statutory basis. All that the court could muster in support of its rejection of the *de minimis* doctrine was that this was Congress's "apparent" intent and that such rigidity represents "at least a comprehensible policy choice." *Id.* at 11a. Such slender reeds are far too weak a basis on which to reject an agency's discretion to apply the well-settled *de minimis* doctrine.

2. Although it spent several pages discussing the legislative history of the Color Additive Amendments of 1960, the court of appeals inexplicably refused to "canvass[] the legislative history of the food additive Delaney Clause" (Pet. App. 26a), which was enacted in 1958. The food additive Delaney Clause is virtually identical to the color additive provision enacted two years later, as the court of appeals acknowledged. Pet. App.

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[14] *See also, e.g.*, Industrial Ass'n of San Francisco v. United States, 268 U.S. 64, 84 (1925); Anderson v. Mount Clemens Pottery Co., 328 U.S. 680 (1946); *cf.* Washington v. Washington State Commercial Passenger Fishing Vessel Ass'n, 443 U.S. 658, 687 n.29 (1979).

26a; *see also* page 4, *supra*.[15] Its legislative history is therefore plainly relevant. *See, e.g., Oscar Mayer & Co.* v. *Evans*, 441 U.S. 750, 756 (1979); *Huddleston* v. *United States*, 415 U.S. 814, 826 (1974). That history unmistakably shows that Congress specifically intended to preserve FDA's inherent discretion to approve substances that present a negligible or *de minimis* risk to humans.

Congress enacted the Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784, 21 U.S.C. § 348, to establish a comprehensive scheme for FDA regulation of substances that are intentionally added to the food supply. Added substances are unlawful under section 402(a)(1) of the FD&C Act if they "may render [the food] injurious to health," and added substances that meet the definition of "food additive" may be used in food only after FDA has approved them as "safe" under section 409, which was added by the 1958 legislation. *See* 21 U.S.C. §§ 321(s), 342(a)(1), 348.

The standard of safety under section 402(a)(1) is whether there is a "reasonable possibility of harm" under actual conditions of use.[16] Congress intended the same standard to apply under section 409, the only difference being that the burden of proving safety was transferred to industry. Congress emphasized that this

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[15] *Compare* 21 U.S.C. § 376(b)(5)(B) *with id.* § 348(c)(3)(A). The only difference is that the color additive clause includes an additional provision governing noningested uses, which requires that any animal studies showing carcinogenicity be "appropriate" for the evaluation of safety in such uses before a substance can be banned. Thus, to the extent there is any difference, the color additive Delaney Clause grants FDA *greater* discretion than the food additive Delany Clause. Since, as discussed in text, Congress did not intend the food additive clause to operate as an absolute bar, it follows *a fortiori* that the color additive clause was not so intended.

[16] This standard derives from the Court's decision in *Lexington Mill*, *supra*, 232 U.S. at 411. *See* Flemming v. Florida Citrus Exchange, 358 U.S. 153, 161 (1958).

standard of safety "does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." [17]

The Delaney Clause was originally enacted in 1958 as a proviso to the general safety standard in section 409. FDA and its parent Department of Health, Education, and Welfare (DHEW) initially opposed inclusion of an anticancer clause on the ground that it was unnecessary in light of the general safety provisions of the legislation, which would of their own force prohibit carcinogenic food additives.[18] The House Interstate and Foreign Commerce Committee then reported a bill that did not contain an anticancer clause on the ground that the public would be adequately protected from possible carcinogens under the general safety provisions.[19]

The bill was amended on the floor of the House to include Representative Delaney's anticancer clause because of Delaney's "deep and abiding interest in this subject." [20] The chairman of the House committee emphasized, however, that the general safety provision of the bill already "includes the matter covered by the Delaney amendment." [21] The administration dropped its opposition to the clause only because it was made clear that the provision incorporated the same standard established by the general safety clause.[22] The Delaney amendment was seen simply as a vehicle "to allay any lingering ap-

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[17] H.R. Rep. No. 2284, 85th Cong., 2d Sess. 4 (1958); S. Rep. No. 2422, 85th Cong., 2d Sess. 6 (1958).

[18] *Food Additives: Hearings Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 85th Cong., 1st & 2d Sess. 38-39 (1957 & 1958).

[19] H.R. Rep. No. 2284, *supra*, at 5.

[20] 104 Cong. Rec. 17414 (1958) (statement of Rep. Harris).

[21] *Id.*

[22] *Id.* at 17415 (letter from DHEW Assistant Secretary Richardson).

prehension . . . of those who desire an explicit statutory mandate on this point." [23]

Like the House, the Senate agreed to the Delaney Clause only on the understanding, as expressed in the Senate report, that "*the bill reads and means the same with or without inclusion of the clause.*" [24] FDA Commissioner Larrick also explained that "the rule of reason would be applied to all materials, cancer producing and otherwise." [25] It was thus universally understood that the Delaney Clause was intended "to focus our attention on the cancer-producing potentialities of various substances," but not to change the standard of reasonableness that FDA would apply to carcinogens under the general safety clause.[26]

This legislative history demonstrates that Congress added the Delaney Clause in 1958 to highlight the national importance of the issue of cancer and to emphasize that FDA should be especially conservative in evaluating the safety of potential carcinogens. The congressional intent was to provide reasonable certainty, consistent with FDA's expert judgment, that an additive would not cause cancer in consumers under its proposed conditions of use in food. The *de minimis* policy, based on quantitative risk assessment, is completely consistent with this legislative design.

The court of appeals simply, and erroneously, ignored the 1958 legislative history. The court compounded this error by misconstruing the legislative history of the 1960 amendments, which added the color additive Delaney

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[23] *Id.*

[24] S. Rep. No. 2422, *supra*, at 11 (emphasis added); *see also, e.g.*, R. Merrill & P. Hutt, *Food and Drug Law* 80 (1980) (" 'the Delaney Clause is utterly irrelevant' ").

[25] W.T. Brady, "Responsibility, Freedom and the Law," 17 Food Drug Cosm. L.J. 323, 326 (1962).

[26] S. Rep. No. 2422, *supra*, at 10-11.

Clause. First, the court dismissed a report of the President's Science Advisory Committee primarily on the ground that it constituted post-enactment legislative history. *See* Pet. App. 18a. In fact, the report had been released prior to House or Senate consideration of the color additive legislation, and it appeared in the record of the House hearings on the bill.[27] The report is significant because it confirms Congress's intent that FDA apply a scientific "rule of reason" in implementing the Delaney Clause.[28]

Second, although the court of appeals acknowledged that the 1960 legislative history was "hardly conclusive" (Pet. App. 19a), it failed to draw the only possible conclusion from that observation—that the interpretation advanced by FDA was therefore a reasonable one, and hence could not be invalidated on judicial review. *See, e.g., Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984). This Court has repeatedly emphasized that FDA in particular must be given ample discretion to interpret the FD&C Act in a workable manner. *See, e.g., Young* v. *Community Nutrition Institute*, 106 S. Ct. 2360, 2364-2365 (1986); *Heckler* v. *Chaney*, 470 U.S. 821 (1985); *United States* v. *Park*, 421 U.S. 658 (1975); *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645 (1973). The court below paid no attention to these teachings.

Finally, the court of appeals ignored the legal context in which the Delaney Clause was enacted, both in 1958 and again in 1960. That context, as explained above, included general recognition of FDA's *inherent* authority to apply the *de minimis* doctrine under the FD&C Act. This doctrine is not merely an abstract matter but is an integral part of the interpretation and implementation of the statute. *See, e.g., United States* v. *Lexington Mill &*

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[27] *See Color Additives: Hearings Before the House Comm. on Interstate and Foreign Commerce*, 86th Cong., 2d Sess. 398 (1960).

[28] *See id.*

Elevator Co., 232 U.S. at 411; *United States* v. *1,500 Cases More or Less, Tomato Paste*, 236 F.2d 208, 215 (7th Cir. 1956) (prohibition against "any" filth in food is not violated by quantities "so low that they are . . . insignificant and of no consequence"); pages 14-15, *supra*, and 23-26, *infra*. Had Congress firmly intended to prohibit application of this settled doctrine under the Delaney Clause, it would expressly have said so. *See, e.g.*, *Midlantic National Bank* v. *New Jersey Dep't of Environmental Protection*, 474 U.S. 494, 501 (1986) ("if Congress intends for legislation to change the interpretation of a judicially created concept, it makes that intent specific"); *Merrill Lynch, Pierce, Fenner & Smith, Inc.* v. *Curran*, 456 U.S. 353, 378 (1982) ("the initial focus must be on the state of the law at the time the legislation was enacted").

3. The court of appeals apparently refused to defer to FDA's interpretation of the statute in part because application of the *de minimis* policy in the circumstances presented here "represented a departure from past agency practice." Pet. App. 6a. While it is true that FDA had not previously applied the *de minimis* doctrine to color additives that were associated with cancer in laboratory animals, the *de minimis* policy is in fact consistent with and the logical outgrowth of FDA's historical regulation of carcinogens. As scientific techniques have advanced, FDA has become more sophisticated in its application of the Delaney Clause to carcinogens. The *de minimis* policy represents the agency's most recent step in this gradual process, which has its roots in administrative practice even before the Delaney Clause was enacted. Judicial deference to the agency is therefore appropriate. *See, e.g.*, *Motor Vehicle Manufacturers Ass'n* v. *State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 42 (1983); *Baltimore Gas & Electric Co.* v. *Natural Resources Defense Council, Inc.*, 462 U.S. 87, 103 (1983) (a "reviewing court must generally be at its most deferential" when the agency has made "predic-

tions, within its area of special expertise, at the frontiers of science").

FDA's evolving implementation of the Delaney Clause has been consistent with the congressional intent that the agency regulate carcinogens with special concern for the public health. The safety standard applied by the agency to carcinogens under both the general safety provisions of the FD&C Act and the Delaney Clause is far stricter than FDA's rule for determining the safe level of a noncarcinogenic substance.[29] Thus, prior to the development of quantitative risk assessment in the early 1970s, FDA consistently interpreted both the general safety clause and the Delaney Clause to require a ban on substances that produced cancer in animals.[30] The agency did not in these cases attempt to determine a *de minimis* level of risk to humans, since the analytical tools to do so were net yet sufficiently developed.

Once those tools became available, FDA has often relied on quantitative risk assessment to permit the use of carcinogens that earlier would have been banned.[31] By

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[29] For noncarcinogenic substances, additives are approved for use in humans at one-hundredth of the "no observed effect level" in animals. *See* 21 C.F.R. § 170.22. This approach has never been used by the agency for animal or human carcinogens, which FDA has always regulated under far more conservative standards. For example, rather than a 100-to-1 safety margin, the margin for D&C Orange No. 17 has been calculated by CTFA to be 420 million to 1. This is an enormous margin of safety.

[30] *See Study of the Delaney Clause and Other Anticancer Clauses* 51-56, *reprinted in Agriculture-Environmental, and Consumer Protection Appropriations for 1975: Hearings Before a Subcomm. of the House Comm. on Appropriations*, 93d Cong., 2d Sess., Pt. 8, at 214-219 (1974).

[31] *See, e.g.*, 38 Fed. Reg. 19226 (1973) (use of carcinogenic drugs in food-producing animals where drug residues present an insignificant risk to humans); 39 Fed. Reg. 1355 (1974) (action levels for unavoidable carcinogenic contaminants set on basis of quantitative risk assessment); 47 Fed. Reg. 14464 (1982) (policy of approving additives containing carcinogenic constituents where human risk is insignificant).

the same token, FDA has never banned a substance under the Delaney Clause where, as here, the risk has been shown to be *de minimis*.[32]

The *de minimis* policy is thus entirely consistent with past administrative practice. As science has advanced, FDA has refined its regulatory standards, and it has departed from prior policies where quantitative risk assessment permits *de minimis* levels of risk to be identified. For example, in 1982, FDA adopted its constituents policy, which allows approval of color additives containing carcinogenic constituents where human risk is insignificant based on quantitative risk assessment.[33] That policy, which represented an express reversal of prior administrative practice under the Delaney Clause, was upheld in *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984) (per curiam), and has since been used numerous times in approving food additives and color additives.

Application of the *de minimis* doctrine to the color additives in this case represents the latest phase in a continuing scientific and regulatory evolutionary process. The court of appeals erred in refusing to defer to the administrative expertise reflected in this process, and instead attempting to straitjacket FDA in science that is now 30 years out of date.

B. Rejection Of The *De Minimis* Policy Produces Absurd Results And Jeopardizes The Food Supply

1. The court of appeals' refusal to permit FDA to apply the *de minimis* policy under the Delaney Clause is not only erroneous—it also entails several absurd results. Most fundamentally, the court ignored FDA's undisputed findings that "no one will contract cancer" from

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[32] For example, FDA's 1977 proposal to ban the artificial sweetener saccharin included an express finding that "saccharin poses a *significant* risk of cancer for humans." 42 Fed. Reg. 19995, 19996 (1977) (emphasis added).

[33] *See, e.g.*, 47 Fed. Reg. 14464, 14465 (1982).

exposure to the additives in question and that such exposure "impose[s] no additional risk of cancer to the public." Pet. App. 86a, 155a. It goes well beyond commendable caution to hold that an anticancer provision absolutely prohibits FDA from approving substances that present "no risk" of cancer to humans. *Id.* at 43a, 106a. Such a result is simply nonsensical. The purpose of the Delaney Clause is to protect human beings, not animals. If there is no risk of human cancer, the statutory purpose cannot be served by banning a substance under this provision.[34]

FDA has consistently avoided such unreasonable results even when they were apparently required under a literal interpretation of the Delaney Clause. For example, calcium, an essential human nutrient, has long been recognized to induce cancer in bulls. *See* C.A. App. 593. Yet FDA has avoided banning calcium in foods by reasoning that the bull is not an appropriate model for humans, even though the Delaney Clause does not contain an express basis for this result. *See also id.* at 488 (describing FDA's refusal to take action against the food additive BHA for similar reasons). It is inconsistent with these results to invalidate application of the *de minimis* policy in this case.

Rejection of the *de minimis* policy also creates irrational distinctions. Substances that come within an exception to the Delaney Clause are permitted in the food supply notwithstanding a demonstrable carcinogenic risk to humans. For example, FDA permits certain levels of aflatoxin in foods such as peanuts, even though aflatoxin is a "potent carcinogen" in humans. *Young* v. *Community Nutrition Institute*, 106 S. Ct. 2360, 2363 (1986); *see* Pet. App. 7a. Similarly, FDA permits the addition of benzo(a)pyrene to meat through broiling, even though

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[34] FDA expressly based its *de minimis* policy on this ground, stating that "there is no gain to the public and the statutory purpose is not implemented or served by an agency action delisting the substance." Pet. App. 77a, 141a.

the lifetime risk of cancer is an order of magnitude greater than one in one million. *See* C.A. App. 612-613. FDA also permits carcinogenic contaminants in color additives and carcinogenic residues of animal drugs in food-producing animals. *See, e.g., Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984) (per curiam); 50 Fed. Reg. 45530 (1985). Additional examples include selenium, PCBs, nitrosamines, and other substances too numerous to mention.[35]

Congress could not have intended to deny FDA discretion to permit use of additives such as D&C Orange No. 17, with an upper-bound human risk of one in 19 billion, in view of the carcinogenic risks that are permitted under various legislative and administrative exceptions to the Delaney Clause. To be sure, regulatory schemes often incorporate subtle and sometimes arbitrary distinctions. But even if FDA might therefore not have been *required* to apply the *de minimis* policy in these circumstances, its attempt to harmonize the statute by relying on that doctrine can hardly be deemed unreasonable.

2. The reasonableness of FDA's *de minimis* policy is confirmed by considering the consequences of rejecting that policy. Advances in testing and analytical technologies have made it increasingly clear that the entire food supply contains animal carcinogens, including essential nutrients, such as vitamins and protein; raw agricultural commodities, such as egg yolk and black pepper; substances added through food processing, such as salt and water (which contains a number of carcinogens); and many other substances. *See* C.A. App. 591-631. Under FDA's comprehensive definition of "food additive," virtually all of these substances could be considered food addi-

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[35] *See, e.g.*, 37 Fed. Reg. 5705 (1972); 38 Fed. Reg. 10458 (1973); 38 Fed. Reg. 18095 (1973); 39 Fed. Reg. 1355 (1974); 46 Fed. Reg. 39218 (1981); 48 Fed. Reg. 57014 (1983); 49 Fed. Reg. 21514 (1984).

tives subject to the Delaney Clause.[36] As just one example, any food that either is washed with water or has water added to it—which encompasses virtually all food—could be considered to contain as food additives the numerous carcinogens identified in drinking water (*id.* at 606-610).

The court of appeals attempted to avoid these implications for the food supply by suggesting that even though the food additive and color additive Delaney Clauses "have almost identical wording" (Pet. App. 26a), they might be interpreted in a different manner. Specifically, the court relied on the significant "social cost of banning . . . [large] parts of the American diet" under the food additive Delaney Clause (*id.* at 27a). Yet nothing in the language or legislative history of the food additive Delaney Clause supports the use of a cost-benefit model for its implementation. Thus, contrary to the court's attempted distinction, its decision in this case will foreclose FDA from applying the *de minimis* policy with respect to food additives, just as it does with respect to color additives.

The court of appeals hypothesized that the exception to the definition of "food additive" for substances generally recognized as safe (GRAS) might provide an escape from application of the Delaney Clause to the general food supply. *See* Pet. App. 26a. If, however, a substance has been shown to induce cancer in animals, it loses its GRAS status and thus becomes subject to the Delaney Clause.[37] In addition, as the court of appeals acknowledged, its reliance on the GRAS exception is based on the

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[36] Under FDA's definition, the term "food additive" encompasses an almost unlimited number of food substances, including substances that are intentionally incorporated into food, substances used to process food, substances that migrate into food from containers or the environment, and raw agricultural commodities that are processed in any way. *See* 21 C.F.R. § 170.3.

[37] *See, e.g.*, 34 Fed. Reg. 17063 (1969) (removing cyclamate from GRAS list); R. Merrill & P. Hutt, *Food and Drug Law* 74 (1980).

assumption that Congress had "adopted inconsistent provisions" in the FD&C Act. *Id.* The agency's interpretation instead harmonizes the statute, and is therefore preferable.

The court of appeals also sought to discount the serious consequences of its decision for the food supply by stating that FDA could seek a change in the law from Congress. This is of course true. Yet the very point demonstrates the irrationality of the court's holding—congressional action would be unnecessary if the court had not imputed such an unreasonable intent to Congress in the first place. Interpretation of a statute to avoid irrational results does not constitute improper judicial amendment but rather conforms to established tenets of statutory construction.

Congress plainly did not intend the absurd results discussed above, and the statute should not be interpreted to require those results:

> All laws should receive a sensible construction. General terms should be so limited in their application as not to lead to injustice, oppression, or an absurd consequence. It will always, therefore, be presumed that the legislature intended exceptions to its language, which would avoid results of this character. The reason of the law in such cases should prevail over its letter.

United States v. *Kirby*, 74 U.S. (7 Wall.) 482, 486-487 (1868); *see also, e.g.*, *American Tobacco Co.* v. *Patterson*, 456 U.S. 63, 71 (1982). These principles apply with special force to the FD&C Act, which "is to be treated as a working instrument of government and not merely as a collection of English words." *United States* v. *Dotterweich*, 320 U.S. 277, 280 (1943).

C. There Is A Conflict In The Circuits

The decision below conflicts with *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984) (per curiam).[38] In *Scott*, the

[38] The decision also conflicts with Monsanto Co. v. Kennedy, 613 F.2d 947 (D.C. Cir. 1979), where the court held that the definition

court upheld FDA's reliance on quantitative risk assessment and the *de minimis* doctrine to approve the color additive D&C Green No. 5, which contains a carcinogenic constituent. The cancer risk to humans from this additive was estimated to lie between one in 30 million and one in 300 million (*id.* at 324), several orders of magnitude greater than the estimated risk from D&C Orange No. 17, which is at issue here. The court in *Scott* concluded that, under the *de minimis* doctrine, FDA did not abuse its discretion in determining that the level of risk presented by D&C Green No. 5 "created no reasonable risk of harm to individuals exposed to the color additive" (*id.* at 325-326), and that approval of the additive was not barred by the Delaney Clause.

The court below attempted to distinguish *Scott* on the ground that only a constituent had been shown to be carcinogenic there, while here the additives themselves are animal carcinogens. Pet. App. 23a-24a. If a constituent of an additive is carcinogenic in isolated form, however, there is no basis for suggesting that it would not also be carcinogenic (at least in similar quantities) in the additive as well. Thus, as the court of appeals admitted (*id.* at 23a), the additive itself should be considered carcinogenic for purposes of the Delaney Clause.[39] The results reached below and in *Scott* are

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of "food additive" contains an implicit *de minimis* exception, which has the effect of excluding from the reach of the Delaney Clause certain substances that present *de minimis* carcinogenic risks. The court below attempted to distinguish *Monsanto* on two grounds, neither of which is convincing. First, the court stated that the substance at issue in *Monsanto*, acrylonitrile, had not been shown to be carcinogenic at the time of the decision in that case. Pet. App. 22a. Nothing in the *Monsanto* opinion, however, suggests that a different result would have been reached had the carcinogenicity of acrylonitrile been established. Second, the court disregarded *Monsanto* because it involved a food additive (Pet. App. 23a & n.13), a distinction that fails for reasons already discussed (pages 25-26, *supra*).

[39] The court of appeals also stated that the "plain language" of the Delaney Clause does not extend to constituents of color addi-

therefore irreconcilable—the Sixth Circuit accepts the *de minimis* doctrine under the Delaney Clause, while the District of Columbia Circuit rejects it.

In addition, the two decisions lead to the anomalous result that useless contaminants may be approved at the one-in-one-million risk level, while useful color additives may not be approved even at the one-in-nineteen-billion risk level. Congress could not have intended such an unreasonable distinction.

D. The Decision Below Has Significant Consequences For Agencies, Industry, And Consumers

The court of appeals' decision is important.[40] As explained above (pages 24-25), invalidation of the *de minimis* policy places the legality of large portions of the food supply in substantial doubt. This cloud should be resolved before manufacturers are forced to make costly and unsatisfactory substitutions in ingredients and processing methods in order to avoid legal challenges. Such substitutions could seriously restrict the choices available to consumers with respect to both food products (which may contain both food additives and color additives) and drugs and cosmetics (which contain color additives). There is no offsetting benefit to the public, since the *de minimis* policy applies only where any risk to humans is so small as to be nonexistent.[41]

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tives. Pet. App. 23a. Since the additive itself is deemed carcinogenic, this is no distinction at all. In addition, as explained above, the *de minimis* doctrine is not based on the statutory language.

[40] Counsel for Public Citizen reportedly described the opinion as "the most important decision ever rendered" under the Delaney Clause. "Court Rejects a Loosening of Curb on Color Additives," New York Times, Oct. 24, 1987, at 8.

[41] Indeed, as the court of appeals remarked, invalidation of the *de minimis* policy could entail "a clear loss for safety." Pet. App. 11a.

In addition, the Delaney Clause has long been the subject of lively debate in administrative, legislative, and academic circles. It is often regarded as a model for other statutes, particularly those addressing environmental risks.[42] FDA's *de minimis* policy under the Delaney Clause is a significant administrative initiative, whose development and refinement have taken several years to complete. The importance of the agency's interpretation of the Delaney Clause strongly counsels review by this Court.

The decision below will affect not only FDA, but also other federal agencies. The Environmental Protection Agency, for example, administers several statutes that can be made workable only by reliance on the *de minimis* doctrine. *See, e.g., California* v. *United States EPA*, 774 F.2d 1437, 1442-1443 (9th Cir. 1985); *Connecticut Fund for the Environment, Inc.* v. *EPA*, 696 F.2d 179, 183 (2d Cir. 1982). The court of appeals' decision in this case casts substantial doubt on the general availability of the *de minimis* doctrine under federal regulatory statutes.[43]

Unless it is reviewed by this Court, the decision below will effectively represent the final resolution of the *de minimis* issue under the Delaney Clause. All FDA decisions under this provision are reviewable in the District of Columbia Circuit, and FDA presumably will conform to that court's decision—we are not aware of any circumstance in which FDA has continued a practice invalidated by an unreviewed decision of a court of ap-

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[42] *See, e.g.*, Turner, *The Delaney Anticancer Clause: A Model Environmental Protection Law*, 24 Vand. L. Rev. 889 (1971).

[43] The court of appeals' rejection of the *de minimis* policy threatens a consistent line of agency decisions. With the exception of nitrosamines in baby bottle nipples, no carcinogen has been banned by a federal agency where the lifetime risk to humans was less than one in one million. *See* Travis, *et al., Cancer Risk Management: A Review of 132 Federal Regulatory Decisions*, 21 Environ. Sci. Technol. 415, 418 (1987).

reals.[44] Review by this Court is warranted for this reason as well.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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[44] An FDA official stated that the decision below "'could very well mean that administrative solutions to create flexibility [under the food additive Delaney Clause] . . . have been exhausted.'" Food Chemical News 36 (Nov. 2, 1987).